

REMARKS

By way of the amendments *supra*, claims 10-13 and 17-30 are canceled without prejudice, and claim 1 are amended. Further, claim 31 is added. Accordingly, claims 1-9, 14-16, and 31 are currently pending in the above-referenced patent application. Applicant respectfully submits no issue of new matter is presented as the amendments have support in the original disclosure.

In the Non-Final Office Action: Restriction is required under 35 U.S.C. §121 and §372. Claims 1, 6, 8, and 14 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,132,755 to Eicher et al. Claims 1, 9-11, 14, and 16 are rejected under 35 U.S.C. §102(b) anticipated by U.S. Publication No. 2002/0082543 to Park et al. Claims 2-4 are rejected under 35 U.S.C §103(a) as being unpatentable over Eicher et al. in view of U.S. Publication No. 2002/0066979 to Kim et al. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. in view of Kim et al., and further in view of U.S. Publication No. 2003/0148291 to Robotti. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. and further in view of Park et al. Claims 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al.

In reply to the Restriction Requirement, Applicant respectfully requests reconsideration.

Regarding the Restriction Requirement, the Examiner indicated that claims 1-30 have two groups of inventions: **group I** (claims 1-16) and **group II** (claims 17-30).

In response to the Restriction Requirement, Applicant affirms election on June 10, 2010 of **group 1** (claims 1-16) without traverse.

In reply to the rejection of claims 1, 6, 8, and 14 under 35 U.S.C. §102(b) as being anticipated by Eicher et al., Applicant respectfully requests reconsideration.

Applicant respectfully submits the asserted Eicher et al. lacks full features of the claimed invention.

Independent claim 1 is amended to incorporate the features of claims 12 and 13.

For instance, independent claim 1 now sets forth, *inter alia*, the following feature:

“...wherein the solidifiable material shrinks during the step of solidifying the solidifiable material, and wherein the shrinking is controlled by the formulation of the solidifiable material or by drying the solidifiable material to reduce an apex angle of the micro-perforator...” (Emphasis added).

On page 4 of the Office Action, it is alleged that Eicher et al. discloses “...solidifying the solidifiable material such that the solidified material in the desired micro-perforator shape...”

However, Eicher et al. fails to disclose that “...the solidifiable material shrinks during the step of solidifying the solidifiable material, and wherein the shrinking is controlled by the formulation of the solidifiable material or by drying the solidifiable material to reduce an apex angle of the micro-perforator...” as recited in amended claim 1. Particularly, Eicher et al. is **silent** about this feature.

Inasmuch as Eicher et al. lacks all of the claim features of the rejected claims, anticipation under 35 U.S.C. §102 cannot be established. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In reply to the rejection of claims 1, 9-11, 14, and 16 under 35 U.S.C. §102(b) anticipated by Park et al., Applicant respectfully requests reconsideration.

Applicant respectfully submits the asserted Park et al. lacks full features of the claimed invention.

Independent claim 1 is amended to incorporate the features of claims 12 and 13.

For instance, independent claim 1 now sets forth, *inter alia*, the following feature:

“...wherein the solidifiable material shrinks during the step of solidifying the solidifiable material, and wherein the shrinking is controlled by the formulation of the solidifiable material or by drying the solidifiable material to reduce an apex angle of the micro-perforator...” (Emphasis added).

On page 5 of the Office Action, it is alleged that Park et al. discloses “...solidifying the solidifiable material such that the solidified material in the desired micro-perforator shape...”

Park et al. fails to disclose that “...the solidifiable material shrinks during the step of solidifying the solidifiable material, and wherein the shrinking is controlled by the formulation of the solidifiable material or by drying the solidifiable material to reduce an apex angle of the micro-perforator...” as the Office Action admitted on page 9.

The Office Action, however, states on page 9 that “it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust a drying rate or polymeric solution formulation introduced in to the mold to control an inherent shrinking of material as the two are result effective variables determining the amount the mass in the mod shrinks.” Accordingly, it appears that the Examiner has taken official notice of the recitation of “wherein the shrinking is controlled by the formulation of the

solidifiable material or by drying the solidifiable material to reduce an apex angle of the micro-perforator." Applicant hereby traverses this official notice and respectfully requests that the Examiner cites a reference to support the assertion or withdraw the rejection.

The Examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970). As set forth in M.P.E.P. § 2144.03, if an applicant traverses an assertion made by an Examiner while taking official notice, the Examiner should cite a reference in support of their assertion.

Further, on page 5 of the Office Action, it is alleged that Park et al. discloses the feature (set forth in **claim 9**) of "...a step of removing air bubbles from the gelling agent or viscous material using positive or negative pressure..."

However, Park et al. does **not** disclose the claimed step of **removing air bubbles from gelling agent or viscous material**. Park et al. merely discloses at paragraph [0146] "...The polymeric material in the mold was then dried and melted **under vacuuming** to form polymeric microneedles..."

Inasmuch as Park et al. lacks all of the claim features of the rejected claims, anticipation under 35 U.S.C. §102 or *prima facie* obviousness under 35 U.S.C. §103 cannot be established. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In reply to the rejection of claims 2-4 under 35 U.S.C §103(a) as being unpatentable over Eicher et al. in view of Kim et al., Applicant respectfully

requests reconsideration.

As noted *supra* and incorporated by reference here, the asserted Eicher et al. lacks the full features of claim 1, whose claimed subject matter is incorporated by reference into dependent claims 2-4.

The secondary reference Kim et al. fails to alleviate the deficiencies in Eicher et al. since it also lacks the very same feature discussed above.

Without conceding the propriety of the asserted combination, one having ordinary skill in the art would not look to combine Eicher et al. and Kim et al. in order to produce the claimed invention insofar as they each lack the same features set forth in the rejected claims.

Inasmuch as the proposed combination of Eicher et al. and Kim et al. lacks all of the claim features of the rejected claims, *prima facie* obviousness under 35 U.S.C. §103 cannot be established. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In reply to the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. in view of Kim et al., and further in view of Robotti, Applicant respectfully requests reconsideration.

As noted *supra* and incorporated by reference here, the asserted Eicher et al. lacks the full features of claim 1, whose claimed subject matter is incorporated by reference into dependent claim 5.

The secondary references Kim et al. and Robotti fail to alleviate the deficiencies in Eicher et al. since these also lack the very same feature discussed above.

Without conceding the propriety of the asserted combination, one having ordinary skill in the art would not look to combine Eicher et al., Kim et al., and Robotti in order to produce the claimed invention insofar as they each lack the same features set forth in the rejected claims.

Inasmuch as the proposed combination of Eicher et al., Kim et al., and Robotti lacks all of the claim features of the rejected claims, *prima facie* obviousness under 35 U.S.C. §103 cannot be established. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In reply to the rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. and further in view of Park et al., Applicant respectfully requests reconsideration.

As noted *supra* and incorporated by reference here, the asserted Eicher et al. lacks the full features of claim 1, whose claimed subject matter is incorporated by reference into dependent claim 7.

The secondary reference Park et al. fails to alleviate the deficiencies in Eicher et al. since it also lacks the very same feature discussed above.

Without conceding the propriety of the asserted combination, one having ordinary skill in the art would not look to combine Eicher et al. and Park et al. in order to produce the claimed invention insofar as they each lack the same features set forth in the rejected claims.

Inasmuch as the proposed combination of Eicher et al. and Park et al. lacks all of the claim features of the rejected claims, *prima facie* obviousness under 35 U.S.C. §103

cannot be established. Accordingly, Applicant respectfully requests withdrawal of the rejection.

In reply to the rejection of claims 12, 13, and 15 under 35 U.S.C. 103(a) as being unpatentable over Park et al., Applicant respectfully requests reconsideration.

Claims 12 and 13 are canceled, and claim 1 is amended to incorporate the features of claims 12 and 13.

As noted *supra* and incorporated by reference here, the asserted Park et al. lacks the full features of claim 1, whose claimed subject matter is incorporated by reference into dependent claim 15.

Without conceding the propriety of the asserted combination, one having ordinary skill in the art would not look to combine park et al. in order to produce the claimed invention insofar as they each lack the same features set forth in the rejected claims.

Inasmuch as the proposed combination of Park et al. lacks all of the claim features of the rejected claims, *prima facie* obviousness under 35 U.S.C. §103 cannot be established. Accordingly, Applicant respectfully requests withdrawal of the rejection.

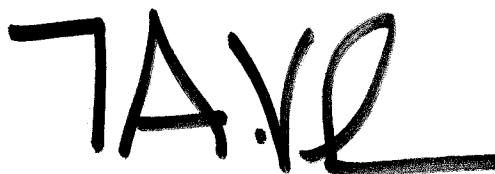
CONCLUSION

Applicant believes that a full and complete response has been made to the Office Action and respectfully submits that all of the stated objections and grounds for rejection have been overcome or rendered moot. Accordingly, Applicant respectfully submits that all pending claims are allowable and that the application is in condition for allowance.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the Applicant's undersigned representative at the number below to expedite prosecution.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'TAV' followed by a stylized flourish.

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